DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

August 8, 1996

Dr. Paul Seligman
Deputy Assistant Secretary
EH6 Building 270CC
U.S. Department of Energy
19901 Germantown Road
Germantown, MD 20874-1290

Dear Dr. Seligman:

Thank you for the telephone conversation earlier this week. I appreciate being able to work with you to resolve the difficulties that have unfortunately arisen between our agencies, and I am encouraged that we can work together to establish a cooperative framework within which these Chernobyl projects can be successfully implemented.

I am pleased to share with you information regarding the two specific items we discussed:

1. Interagency Agreement - This currently is being drafted, together with an attachment that defines relevant terms. We plan to send the draft document to you for your consideration next week.

2. Leukemia Protocol - Enclosed are copies of the Leukemia Protocol (Enclosure A) and the report from the chairman of the peer review committee (Enclosure B). The reports of both the NCI and Ukraine Institutional Review Boards (IRB) currently are being forwarded to the NIH Office for Protection from Research Risks (OPRR) for final approval. Once a Single Project Assurance (SPA) number has been approved and received from OPRR, we will transmit a copy to you. Upon receipt of an SPA, NCI regards as complete the approvals required prior to signing and funding agreements with Ukraine to implement Phase I of the leukemia study (i.e., the 18-month feasibility study). All of the relevant available documentation for the leukemia study (Enclosures A and B above) and the two thyroid studies (protocol, peer review and SPA documents) have been provided to your staff previously.

   While we regard the leukemia protocol itself as inviolate, at least until the feasibility study demonstrates the need for modification and both countries agree to such modification, the appendices (e.g., budget, personnel and equipment needs) are subject to continuing revision as circumstances change. Within a few days we hope to provide you with our current best estimate of financial needs, including "local assistance," for this project. (As we develop a work scope and budget estimate for an NCI support contract, we will attempt, to the extent possible, to distinguish between costs associated with the leukemia study and the thyroid studies.)

We also expect that the feasibility of implementing the more major Phase II of the study will be apparent prior to the completion of Phase I so that, assuming that Phase II is justified, the study might continue with minimal interruption. If so, preparation of a Phase II protocol will begin as soon as its need becomes apparent. (We will be working with our Ukrainian colleagues to develop criteria to assist in making this decision.) To that end, the IRBs and OPRR have looked at the entire project in order to avoid future delay; peer review for a Phase II will be necessary, however.

Also, it is our intention that Dr. Ihor J. Masnyk will be the primary NCI point of contact at the DOE staff level. When an NCI support contract for the leukemia and both thyroid projects is executed, it is expected also that he will be the project officer. And, as we discussed, it is expected that NCI will be the sole source of interaction with the Belarussian and Ukrainian governments regarding all aspects of these projects; eventually Dr. Masnyk is expected to be the principal point of contact in this area also.

In addition, a proposed Letter Arrangement for Cooperation for signing an agreement with Ukraine to implement Phase I of the leukemia study is appended to this letter (Enclosure C). We would appreciate your review and comments prior to sending it to other U.S. agencies and to Ukrainian authorities. This draft is based upon the previous implementation agreements for the thyroid studies (Enclosures D and E), with appropriate modifications. Your prompt response would be appreciated so that we might proceed to process the document among all parties. (The inclusion of the Nuclear Regulatory Commission on this document has yet to be confirmed.)

I hope that this information is responsive to your requests and helpful for your immediate needs. Please let me know if I can be of further assistance in our efforts to proceed to carry out these important studies.

Sincerely,

Faye C. Austin, Ph.D.
Director, Division of Cancer Biology

Enclosures (5)

Attachment 2

LETTER ARRANGEMENT FOR COOPERATION BETWEEN THE UNITED STATES NATIONAL CANCER INSTITUTE, DEPARTMENT OF ENERGY AND NUCLEAR REGULATORY COMMISSION AND THE MINISTRY OF HEALTH AND THE ACADEMY OF MEDICAL SCIENCES OF UKRAINE ON THE IMPLEMENTATION OF THE SCIENTIFIC PROTOCOL FOR THE STUDY OF LEUKEMIA AND OTHER HEMATOLOGIC DISEASES AMONG CLEAN-UP WORKERS IN UKRAINE FOLLOWING THE CHERNOBYL ACCIDENT

Pursuant to the Memorandum of Cooperation in the field of Civilian Nuclear Reactor Safety between the United States of America and Ukraine, the United States National Cancer Institute, Department of Energy and Nuclear Regulatory Commission, and the Ministry of Health and the Academy of Medical Sciences of Ukraine agree to implement Phase I of the Scientific Protocol for the Study of Leukemia and Other Hematologic Diseases Among Clean-Up Workers in Ukraine Following the Chernobyl Accident according to its specific provisions and according to the following general responsibilities:

1. The Ministry of Health of Ukraine, in conjunction with the Academy of Medical Sciences of Ukraine, shall provide Ukrainian medical, scientific, technical and support personnel, their salaries and such facilities and space as may be needed for the study, including project office space for visiting U.S. scientific and medical personnel; and

2. The United States National Cancer Institute, in conjunction with the Department of Energy and the Nuclear Regulatory Commission, shall provide to Ukraine such supplementary equipment and supplies as may be needed to carry out Phase I of these studies, relevant medical, scientific and technical consultation, and training and supplemental salary support, as appropriate, for Ukrainian personnel assigned to Phase I of the study.

The undersigned recognize that the implementation of Phase I of this Scientific Protocol is in the interest of both countries, and of the world scientific community, in the expectation that it will lead to a Phase II major study of hematologic disease of the clean-up workers by (a) providing new scientific information on the etiologic role of ionizing radiation in causing hematologic disease, (b) providing a basis for studies of clean-up workers aimed at other than hematologic disease, and (c) contributing to public health policy in regard to the medical care of clean-up workers and to the prevention and early detection of disease among them.

Signed this (day) of (month), 1996, in Bethesda, Maryland, USA.

For the United States
National Cancer Institute

For the Ministry of Health of Ukraine

For the United States
Department of Energy

For the Academy of Medical Sciences
of Ukraine

For the United States
Nuclear Regulatory Commission

ATTACHMENT 3

15 Aug 96

Elaine:

Thank you for your note of 12 Aug.

Let me start by addressing the three points in your second paragraph:

1. We are trying to determine when exactly the work on Ukraine thyroid project has really started. There are different versions and different conceptions about when a project starts. We at NCI did also hear that Dr. Tronko started the project immediately after signing the Financial Arrangement on 3 Jun 96. Incidentally, some of his collaborators expressed the view that receipt of equipment and supplies was necessary in order to start working on the milestones. Others may have believed that the project starts only after the funds for local support have been transferred and received locally. Obviously this point needs clarification.

Dr. Tronko and Dr. Tereshchenko are presently on their vacations; Dr. Tereshchenko will return to Kyiv on Monday 19 August and I will discuss this issue with him.

2. We are indeed finalizing projections of the milestones for the next quarter. This will be coordinated with our Ukrainian colleagues and submitted to you, I hope, in time to make it possible to prepare all the paperwork needed for payment of the next installment. The second quarter milestones can't be completely finalized until we see the first quarter report.

3. In the same vein, we will work with our counterparts to assure timely submission of the report for the past quarter and an invoice of projected work for the next.

The issue of clinical chemistry is more problematic. During the protocol development, when all these assays were specified, fund levels were not an issue. They became a part of the protocol and now we have a problem of matching assays to available funds. There are serious arguments pro and con that we cannot afford all of these assays, and that we should not miss this unique opportunity to obtain this material. Now several options have been proposed but they are opinions of individuals and not a consensus of a group, certainly not a decision of the oversight group we are in process of establishing.

We are planning a meeting of several of our advisors on this topic to help us to establish position on this issue. Perhaps in October the Binational Advisory Group will change the protocol, but in the meantime we need a basis to act reasonably without having to regret anything in the future. Lletters of invitation to serve on the Advisory Group have already been mailed to the proposed U.S. candidates, so we should have this group established soon.

Our job at present is to hold the course but proceed carefully. I expect drastic cuts in the original list of assays but we still must act according to established rules. I understand Sheilah's concern about buying in bulk and planning ahead, but in this category of expendable supplies (some with limited shelf life) we should not build up large inventories. Frankly I doubt that the projects will be ready for actual clinical chemistry testing before Oct-Nov. To prepare for such eventuality, however, we may procure one deep freezer for each organization an start saving specimens for future analysis. It probably would prove to be cost-effective.

Returning to the first issue of whether we should pay Dr. Tronko the second installment for the local support. I think we should. Even if we find that the project may not have started

exactly on 3 June, we could adjust the timing later. In the meantime, whatever momentum they may have generated, should be maintained.

On another topic, recently we have noticed from forwarded E-mail messages that Dr. Larissa Anspaugh made several call to senior project staff in Minsk. Can you tell us whether these calls were made in any official capacity that you might have assigned her, and if that is the case, please forgive me for bringing up this issue but, at the same time, could you advise us what that official capacity might be? In any case, I am worried that , if too many individuals start calling on our behalf (even with maximum good will), we will have more confusion in Belarus and Ukraine. Could you please clarify this for us?

Ihor

Attachment 4

Dose Reconstruction Program

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EQUIPMENT AND SUPPLY BUDGET

12-MONTH COST ESTIMATE

	BELARUS k$	UKRAINE k$
DOE Capital Equipment Funds (FY 96)	125.7	125.7
Cost including liens through July	78.7	119.5
FUNDS AVAILABLE	**47.0**	**6.2**
NRC Funds (FY 96)	265.2	500.0
Cost including liens through July	95.3	58.2
FUNDS AVAILABLE	**169.7**	**441.8**
TOTAL FUNDS AVAILABLE	**216.7**	**448.0**
12-Month Estimate for E & S Requests Not including cost for test kits	209.4	732.4
Total Funds Available minus Estimate	**7.3**	**-284.4**
First year's costs for clinical chemistry according to the Protocol specifications	142.7	1281.8
The Bottom Line	**-135.7**	**-1,566.2**

As noted above, there is a shortfall of about $2,000,000 for supplies and equipment in order to implement the first 12 months of the projects according to the Protocols and according to the equipment and supply lists that have been received at LLNL. (Note: NCI has approved only a small portion of the requested equipment and has not asked that test kits, other supplies, and equipment be

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purchased for the performance of clinical chemistry analyses.) Clearly, some cost containment is in order, both in terms of scaling back the equipment requests and in reducing the clinical chemistry tests as stated in the Protocols. (Please refer to a separate fax from Lynn Anspaugh on the clinical chemistry issue.)

Following are four pages that show the breakdown by country and group for the equipment and supply requests for the first twelve months (in the case of Ukraine and the next twelve months for Belarus). We will send via mail (there are too many pages to fax) the requests from each country, group, and justifications for equipment.

Belarus

From DOE and NCI (I recall being told by NCI that discussions took place with people in Belarus regarding this matter), I need a clear understanding of what the "administrative" part of funding support is to cover as far as equipment, supplies, services, and equipment maintenance are concerned. For example, we have specifically advised that LLNL will no longer cover expenses for e-mail services once the funding agreement was in place and they received monies.

Ukraine

Again, from DOE and NCI I need a clear understanding of what the "administrative" part of the funding support is to cover. Thus far, I have explained our business practices in Belarus (regarding e-mail, etc.) or types of items we will or will not purchase and the Ukrainians seem to be receptive Although we have already begun some purchasing activities for Ukraine, we are now at the same point for the equipment and supply process where I was asked to join the activities of the FRETTERS for the purchase of equipment and supplies for the Belarus thyroid protocol. At that time a meeting was convened by NCI (FRETTERS, Mincey, Mitchell, and Hendrickson) where I received several E & S lists from various American team members; the wish list from Belarussians and Russians (via Americans); and decisions were made for phase 1 and phase 2 purchases, the "on hold" listing, and additions and deletions of items. From that point, I was then able to work with individuals for the specifications of required equipment.

As indicated above, I believe it is time for the American team to convene a meeting to review, discuss, and decide on the requested equipment for Ukraine and discuss the plan of action for Belarus. This is especially important, as we have not received (as requested at our May 13 meeting at NCI) a project-implementation schedule with indications of required equipment delivery for both projects. As I am neither a scientist nor a medical person, information, education, and guidance from various American team members for the Ukraine project is needed so that I can perform and fulfill my part of this project.

I request clarification of "administrative" funding support from DOE and NCI and request a response from NCI regarding the above mentioned meeting.

Sheilah Hendrickson LRA

Sheilah Hendrickson